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FORM PTO-1449

FIRST SUPPLEMENTAL
INFORMATION DISCLOSURE STATEMENT

ATTY. DOCKET NO.
2057.0090003/JAG/BJD

APPLICATION NO.
09/839,946

APPLICANT
Williams et al.

FILING DATE
April 19, 2001

GROUP
1652

U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
JKP	AA2	4,917,888	04/17/1990	Katre et al.	424	85091	12/11/1987
JKP	AB2	5,428,128	06/27/1995	Mensi-Fattohi et al.	530	302	09/27/1994
JKP	AC2	5,643,575	07/01/1997	Martinez et al.	424	1941	10/27/1993
JKP	AD2	5,919,455	07/06/1999	Greenwald et al.	424	1781	03/20/1997
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EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
JKP	AL2	WO 00/07629 A2	02/17/2000	WIPO			Yes No
JKP	AM2	WO 00/08196 A2	02/17/2000	WIPO			Yes No
JKP	AN2	WO 01/59078 A2	08/16/2001	WIPO			Yes No
	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

JKP	AR	10	Alvares, K., et al., "Rat urate oxidase produced by recombinant baculovirus expression: Formation of peroxisome crystallloid core-like structures," Proc. Natl. Acad. Sci. USA 89:4908-4912, National Academy of Sciences (1992).
JKP	AS	10	Braun, A., and Alsenz, J., "Development and Use of Enzyme-Linked Immunosorbent Assays (ELISA) for the Detection of Protein Aggregates in Interferon-Alpha (IFN- α) Formulations," Pharm. Res. 14:1394-1400, Plenum Press (October 1997).
JKP	AT	10	Braun, A., et al., "Protein Aggregates Seem to Play a Key Role Among the Parameters Influencing the Antigenicity of Interferon Alpha (IFN- α) in Normal and Transgenic Mice," Pharm. Res. 14:1472-1478, Plenum Press (October 1997).

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	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

<i>JK</i>	AR	<u>11</u>	Caliceti, P., et al., "Biopharmaceutical Properties of Uricase Conjugated to Neutral and Amphiphilic Polymers," <i>Bioconj. Chem.</i> 10:638-646, American Chemical Society (1999).
<i>JK</i>	AS	<u>11</u>	Chen, R.H.-L., et al., "Properties of Two Urate Oxidases Modified by the Covalent Attachment of Poly(Ethylene Glycol)," <i>Biochim. Biophys. Acta</i> 660:293-298, Elsevier/North-Holland Biomedical Press (1981).
<i>JK</i>	AT	<u>11</u>	Colloc'h, N., et al., "Crystal Structure of the protein drug urate oxidase-inhibitor complex at 2.05 Å resolution," <i>Nature Struct. Biol.</i> 4:947-952, Nature America, Inc. (November 1997).

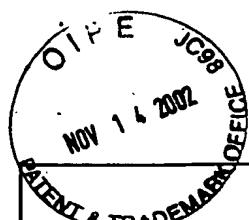
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	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

SJS	AR	<u>12</u>	Conley, T.G., and Priest, D.G., "Thermodynamics and Stoichiometry of the Binding of Substrate Analogues to Uricase," <i>Biochem. J.</i> 187:727-732, The Biochemical Society (1980).
	AS	<u>12</u>	Fuertges, F., and Abuchowski, A., "The Clinical Efficacy of Poly(Ethylene Glycol)-Modified Proteins," <i>J. Contr. Rel.</i> 11:139-148, Elsevier Science Publishers (1990).
SJS	AT	<u>12</u>	Henney, C.S., and Ellis, E.F., "Antibody Production to Aggregated Human γ -Globulin in Acquired Hypogammaglobulinemia," <i>N. Engl. J. Med.</i> 278:1144-1146, Massachusetts Medical Society (1968).

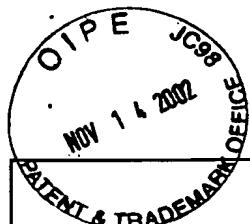
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<i>JG</i>	AR	<u>13</u>	Hershfield, M.S., et al., "Use of site-directed mutagenesis to enhance the epitope-shielding effect of covalent modification of proteins with polyethylene glycol," Proc. Natl. Acad. Sci. USA 88:7185-7189, National Academy of Sciences (1991).
	AS	<u>13</u>	Ito, M., et al., "Identification of an Amino Acid Residue Involved in the Substrate-Binding Site of Rat Liver Uricase by Site-Directed Mutagenesis," Biochem. Biophys. Res. Commun. 187:101-107, Academic Press, Inc. (1992).
<i>JG</i>	AT	<u>13</u>	Kelly, S.J., et al., "Diabetes Insipidus in Uricase-Deficient Mice: A Model for Evaluating Therapy with Poly(Ethylene Glycol)-Modified Uricase," J. Am. Soc. Nephrol. 12:1001-1009, Lippincott Williams & Wilkins (2001).

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	AR	<u>14</u>	Kito, M., et al., "A Simple and Efficient Method for Preparation of Monomethoxypolyethylene Glycol Activated with p-Nitrophenylchloroformate and Its Application to Modification of L-Asparaginase," <i>J. Clin. Biochem. Nutr.</i> 21:101-111, Institute of Applied Biochemistry (1996).
	AS	<u>14</u>	Kunitani, M., et al., "Classical light scattering quantitation of protein aggregates: off-line spectroscopy versus HPLC detection," <i>J. Pharm. Biomed. Anal.</i> 16:573-586, Elsevier Science (December 1997).
	AT	<u>14</u>	Lee, C.C., et al., "Generation of cDNA Probes Directed by Amino Acid Sequence: Cloning of Urate Oxidase," <i>Science</i> 239:1288-1291, American Association for the Advancement of Science (1988).

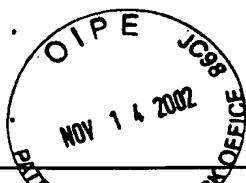
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	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	<u>15</u>	Mahler, H.R., et al., "Studies on Uricase: I. Preparation, Purification, and Properties of a Cuproprotein," <i>J. Biol. Chem.</i> 216:625-641, American Society of Biological Chemists, Inc. (1955).
	AS	<u>15</u>	Montalbini, P., et al., "Uricase from leaves: its purification and characterization from three different higher plants," <i>Planta</i> 202:277-283, Springer-Verlag (July 1997).
	AT	<u>15</u>	Moore, W.V., and Leppert, P., "Role of Aggregated Human Growth Hormone (hGH) in Development of Antibodies to hGH," <i>J. Clin. Endocrinol. Metab.</i> 51:691-697, The Endocrine Society (1980).

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Tr. Saintha

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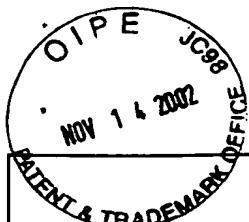
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<i>JH</i>	AR	<u>16</u>	Mountain View Pharmaceuticals, Inc., "PURICASE®," U.S. Trademark Registration Number 2,246,623 (report obtained from U.S. Trademark Electronic Search System (TESS), December 5, 2001).
	AS	<u>16</u>	Osman, A.M., et al., "Liver Uricase in Camelus dromedarius: Purification and Properties," <i>Comp. Biochem. Physiol.</i> 94B:469-474, Pergamon Press (1989).
	AT	<u>16</u>	Palleroni, A.V., et al., "Interferon Immunogenicity: Preclinical Evaluation of Interferon- α 2a," <i>J. Interferon Cytokine Res.</i> 17 (Suppl 1):S23-S27, Mary Ann Liebert, Inc. (July 1997).

EXAMINER *T. Sarath* DATE CONSIDERED *9/9/03*

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<i>JG</i>	AR	17	Porstmann, B., et al., "Comparison of Chromogens for the Determination of Horseradish Peroxidase as a Marker in Enzyme Immunoassay," <i>J. Clin. Chem. Clin. Biochem.</i> 19:435-439, Walter De Gruyter & Co. (1981).
	AS	17	R&D Focus Drug News (DataStar File IPNR/IPNA), Accession No. 1998:2984 DRUGNL, "PEG-uricase BioTechnology General, Duke University, Mountain View licensing agreement," August 24, 1998.
<i>JG</i>	AT	17	Savoca, K.V., et al., "Induction of Tolerance in Mice by Uricase and Monomethoxypolyethylene Glycol-Modified Uricase," <i>Int. Archs. Allergy Appl. Immunol.</i> 75:58-67, S. Karger Medical and Scientific Publishers (1984).

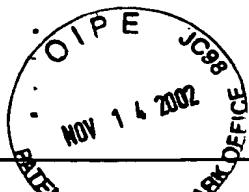
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<i>JS</i>	AR	18	Suzuki, H., and Verma, D.P.S., "Soybean Nodule-Specific Uricase (Nodulin-35) Is Expressed and Assembled into a Functional Tetrameric Holoenzyme in <i>Escherichia coli</i> ," <i>Plant Physiol.</i> 95:384-389, American Society of Plant Physiologists (1991).
	AS	18	Wu, X., et al., "Two Independent Mutational Events in the Loss of Urate Oxidase During Hominoid Evolution," <i>J. Mol. Evol.</i> 34:78-84, Springer-Verlag (1992).
<i>JS</i>	AT	18	Yeldandi, A.V., et al., "Human Urate Oxidase Gene: Cloning and Partial Sequence Analysis Reveal a Stop Codon within the Fifth Exon," <i>Biochem. Biophys. Res. Commun.</i> 171:641-646, Academic Press, Inc. (1990).

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